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September 15, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane, rm. 1061
Rockville, MD 20852

Re: Request for Extension for Submission of Comments;
Docket No. 00D-1392

To whom it may concern:

We are writing to request a 90 day extension of time for submission of comments on FDA's draft guidance for industry entitled "Botanical Drug Products," which was announced in the Federal Register of August 11, 2000, 65 Fed. Reg. 49247.

This request comes on behalf of a research-based company based in Asia that only recently received notice of the guidance document. This company has important botanical efforts underway and intends to submit comments. They are in the midst of research and wish to amass data prior to making the submission. The company is particularly interested in exploring the development of an OTC Monograph for botanical products.

Sincerely,

Diane C. McEnroe/ap

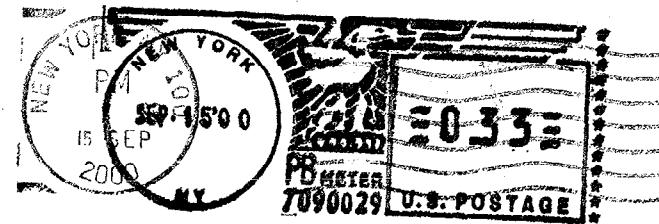
Diane C. McEnroe

cc: I. Scott Bass

00D-1392

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